APPENDIX D: DEVELOPMENT OF COSTS FOR THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

GENERAL METHODOLOGY

The costs associated with the process for the review of human drug applications are based on obligations recorded within CDER, CBER, ORA, and HQ. These organizations correspond to the cost categories presented as follows:

Cost Category	FDA Organization
Costs for the Review of NDAs, BLAs, and Supplements	CDER
Costs for the Review of BLAs and Supplements	CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	HQ

The costs for each component are shown in tables 7 and 8 on pages 11-12. They were derived using time-reporting systems in CDER, CBER, and ORA, and were calculated for HQ as described in more detail in this appendix. Using the definitions of costs and activities included in the process for the review of human drug applications in PDUFA, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the human drug application review process.

CENTER COSTS

Costs of the human drug application review program are tracked for each organizational component in CDER and CBER, usually at the division level. Most FDA components involved in the process perform a mixture of activities – some within the definition of the process for the review of human drug applications, and some not. FDA groups its organizational components into three categories:

- direct review and laboratory
- indirect review and support
- Center-wide costs

The allocation of costs for each category is discussed below.

Direct Review and Laboratory

Employees in all components of CDER and CBER, other than those noted below as Center indirect review and support components, are required to report their time for a total of eight weeks (two weeks per quarter) each fiscal year in activity-based time reporting systems. The activities in the systems differentiate between time spent on the process for the review of human drug applications and all other time, so that time reported can be separated into allowable and excluded activities as defined by PDUFA.

FDA is a payroll-intensive organization – about 52 percent of all FDA funds pay for employee salaries and benefits, and almost all other costs are directly supporting these employees. Thus the average percentage of time reported on human drug review process activities in CDER and CBER is applied to all costs incurred for the entire fiscal year in those Centers. This method provides an estimate of each cost centers' costs incurred while conducting human drug review activities in FY 2013.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDER, these components include portions of the Office of the Center Director, the Office of Strategic Programs, the Office of Management, the Office of Communications, and the Office of Executive Programs. In CBER, these components include portions of the Office of the Center Director, Office of Management, and the Office of Communications, Outreach and Development. Most employees of these components do not report their time.

FDA assumes the time of management and administrative personnel supporting the process for the review of human drug applications is equivalent to the proportion of time Center employees in direct review and laboratory components spend on human drug review process activities. Thus the average percentage of time expended on human drug review activities for all direct review and laboratory components in FY 2013 was applied to all costs incurred for the entire fiscal year by the indirect review and support components.

Center-Wide Costs

A number of Center-wide and Agency-wide expenses are paid from the central accounts of the Center or of FDA rather than from funds allocated to a specific Center or division or office within the Center. These costs include rent, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. A percentage of these Center and FDA-wide costs are chargeable to the process for the review of human drug applications. That percentage is either a specific amount that is supported by independent documentation or is the amount of time reported for allowable activities (direct and indirect) in the Center, as a percentage of total time reported for all Center direct and indirect activities.

As in prior years, resources expended in FY 2013 by the Office of Shared Services in supporting the human drug application review process are reported as if they were incurred in CDER, CBER, ORA, or HQ.

FIELD INSPECTION AND INVESTIGATION COSTS

ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the "field") and headquarters offices, which are tracked in the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system that captures time spent in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the review process for human drug applications.

Total direct hours reported in FACTS are used to calculate the total number of FTEs required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by ORA administrative and management personnel. The Agency then multiplies the total number of FTEs used in the process for the review of human drug applications by the average salary and benefits cost in ORA to arrive at ORA salary and benefit costs for work that is a part of the process for the review of human drug applications as defined in PDUFA. The final step is to allocate ORA obligations for operations and rent to the human drug review activities based upon the ratio of user fee related FTEs to total ORA FTEs.

Table 13 summarizes the calculation of ORA costs for the process for the review of human drug applications for FY 2012 and FY 2013.

TABLE 13: OFFICE OF REGULATORY AFFAIRS COSTS OF THE REVIEW PROCESS FOR HUMAN DRUG APPLICATIONS AS OF SEPTEMBER 30, 2012 AND 2013

COST COMPONENT	FY 2012	FY 2013
FTE Utilized	163	147
ORA Average Salary and Benefits	$114,268	$117,355
Total Salary and Benefits	$18,625,684	$17,251,185
Operating and Other Costs	$18,560,801	$14,257,051
TOTAL	**$37,186,485**	**$31,508,236**

ORA costs for the process for the review of human drug applications described above include total process costs, including costs paid from appropriations and costs paid from fee revenues.

AGENCY GENERAL AND ADMINISTRATIVE COSTS

The Agency general and administrative costs include all costs incurred in FDA's HQ that are attributable to the Office of the Commissioner and all other FDA headquarters components that are not Centers or the Office of Regulatory Affairs. For the purpose of these calculations, HQ is considered to comprise the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Legislation
- Office of Policy and Planning
- Office of External Affairs
- Office of the Executive Secretariat
- Office of the Chief Counsel
- Office of Minority Health
- Office of Women's Health
- Office of the Chief Scientist (excluding the National Center for Toxicological Research)
- Office of Operations
- Office of Foods and Veterinary Medicine (excluding the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine)
- Office of Medical Products and Tobacco (excluding the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Device and Radiological Health, and the Center for Tobacco Products)
- Office of Global Regulatory Operations and Policy (excluding the Office of Regulatory Affairs)

In summary, the HQ costs include all of FDA except for the six product-oriented centers, the Office of Regulatory Affairs, and the National Center for Toxicological Research.

The HQ costs applicable to the process for the review of human drug applications were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total HQ costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from HQ. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the process for the review of human drug applications in CDER, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated $81,794,065 in general and administrative costs to the human drug review process in FY 2013. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for the process for the review of human drug applications. General and administrative costs are approximately 8.5 percent of FY 2013 total human drug review process costs.